K030856

SECTION 3. 510(k) SUMMARY

MAR 2 8 2003

- **Substantially Equivalent (SE) To: Ambulatory Devices**

Braemar Model ER700
510(k) K981394

Biosensor Model 1005
510(k) K950944

Braemar Model DXP1000
510(k) K993618

Modification Background

The essence of this modification is a change to the recorder hardware to a smaller configuration with reduced power consumption and to reinstate existing arrhythmia functionality to maintain competitiveness with other devices within the domestic marketplace. In connection with the modification the device performance has been validated as reported herein. Note all devices meet the same performance standards of AAMI-EC38, EN60601-1-1, EN60601-1-2, and EN60601-2-47.

The above changes do not affect the intended use of the device or alter the fundamental scientific technology of the device as is demonstrated in this submission.

- **Comparison To The SE Devices:**

Attribute	ER800	ER700	Model 1005	DXP1000
Storage capacity	Up to 30 minutes, Looping Memory	Up to 30 minutes, Looping Memory	1 day, 24 hours	2 days, 48 hours
Memory type	Flash (non-volatile)	Flash (non-volatile)	Flash (non-volatile)	Compact Flash (non-volatile)
On-board analysis	Yes	No	Yes	No
Liquid Crystal Display (LCD)	No	Yes	No	Yes
Data transfer method	TTP Transtelephonic	TTP or RS232 Serial	Bi-directional parallel I/O	USB I/O
Pacemaker detection & reporting	Yes	No	Yes	Yes
Belt clip	Yes	No	No	Yes
Battery	One AA	Two AAA	Four AA	Two AA
Battery Life	30 days	14 days	24 hours	48 hours

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

Braemar, Inc.
c/o Mr. David Norberg
Regulatory Affairs Representative
11481 Rupp Drive
Burnsville, MN 55337

Re: K030856
Trade Name: ER800 Series ECG Event Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: March 12, 2003
Received: March 18, 2003

Dear Mr. Norberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030856

SECTION 4. INDICATIONS FOR USE, INTENDED USE

Indications for Use:
(No change from predicate devices)

To record infrequent and elusive ECG heart arrhythmia data. Once data is recorded, patients transmit the recorded ECG data over the telephone or directly to a host PC for review.

The electrocardiogram (ECG) is a graphic description of the electrical activity of the heart. This activity is recorded form the body surface by a group of electrodes positioned at predefined places to reflect the activity from different perspectives. Depending on how these electrodes are placed, the ECG waveforms are considered as separate linearly dependent signals. Presently the ECG is the most prominent and widely used non-invasive cardiac diagnostic technique. There exists a significant accumulation of correlated clinical data, which provides a powerful basis for evaluation of these biophysical signals.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030856

Prescription Use Only